

Will U.S. Try to Circumvent Drug Firms Patent?

By Mark S. Sullivan Medill News Service - Chicago Daily Herald

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The furor over Abbott Laboratories' 400 percent price increase last December of the AIDS drug Norvir has resulted in an unprecedented meeting at the National Institutes of Health to consider circumventing the drug giant's patent.

Pressure from numerous AIDS groups and a letter from eight members of Congress, including Illinois Democrat Jan Schakowsky, led Health and Human Services Secretary Tommy Thompson to call for the Tuesday meeting in Bethesda, Md.

After the meeting, Thompson could decide to allow production and marketing of a generic version of Norvir 10 years in advance of the expiration of Abbott's patent.

Jeff Lieden, president and chief operating officer of pharmaceutical products, will represent Abbott, along with company attorneys and public relations officers.

Because Norvir was developed using NIH grants in the early '90s, the federal government may act on language in the 1980 Bayh-Dole Act stating that such drugs must be "available to the

public on reasonable terms." The legal debate centers on differing interpretations of that language.

Significantly, the act's co-author, former Indiana Sen. Birch Bayh, is expected to speak on Abbott's behalf at Tuesday's meeting.

Abbott does not believe that its patent is in any legal danger.

"There is absolutely no legal basis in Bayh-Dole for the government to march-in in this case," said Dr. John Leonard, head of drug development at Abbott. "Bayh-Dole is about making the product available -- and the product is already available. The law has nothing to do with price."

"We will defend our patent vigorously," Abbott spokeswoman Jennifer Smoter said.

A group of U.S. senators led by John McCain of Arizona Wednesday called on the Federal Trade Commission to probe Abbott's price hike for possible anti-trust violations.

"It would be unconscionable if drug manufacturers are taking such unscrupulous actions to maximize their bottom line, at the expense of patients suffering with AIDS," McCain said in a statement.

Smoter stressed that the NIH contributed only \$3.4 million of the \$300 million-plus Abbott spent to develop and approve Norvir, and that the Bayh-Dole Act was never intended to set price controls on drugs the government helped develop.

In their letter to Thompson, the representatives assert that Abbott's development costs for Norvir were relatively low due to short clinical trials and a quick, 70-day evaluation and approval by the Food and Drug Administration. Meanwhile, they say, total sales topped \$1 billion by the end of 2001.

On January 29, approximately one month after Abbott increased Norvir's price, public interest group Essential Inventions asked Thompson to use his authority under Bayh-Dole to allow generic manufacture of Norvir.

"If the Bush Administration allows the 400 percent price hike to stand, it sends a signal that there is no limit to how high you can price a government-funded invention," said James Love, president of Essential Inventions.

Love said after the meeting Thompson may apply pressure to Abbott to back down on the price increase while allowing it to keep its patent intact, an outcome Love said might be best for all concerned.

Details of Tuesday's proceedings are unclear. No agenda has been released and the NIH refused to say if Abbott's Lieden will speak.

"We are just going to hold the meeting and see what happens," NIH public affairs officer Marc Stern said Wednesday.

Under the new price, a month's supply of the widely-used Norvir increased from \$52 to \$257, sparking the ire of the AIDS community. Abbott kept Norvir's price the same for people who get the drug through state-sponsored health programs and it has programs to provide it free to people in need who don't have insurance or state help.

Norvir is a remarkably effective antiretroviral drug used to stop the spread of HIV. It is now most commonly used to amplify the effects of other, newer AIDS drugs of the same class, called protease inhibitors. This usage requires a much smaller dosage; consequently, Norvir's sales fell to \$100 million last year from a high of \$250 million in 1998.

Lawmakers, AIDS doctors and advocacy groups have suggested Abbott raised the price to push people to use Abbott's new protease inhibitor, Kaletra, which already contains Norvir as a

built-in "boosting agent."

Competing protease inhibitors also perform far better when combined with Abbott's Norvir, which doctors must prescribe separately -- now at five times the cost. The net result: Abbott's Kaletra is now the lowest priced clinically approved AIDS regimen.

"I believe this is an overt move by Abbott to pressure physicians into prescribing Kaletra," said Dr. Frank Palella, assistant professor in infectious diseases at Northwestern University's Feinberg School of Medicine. "My decision to prescribe a medication should not be based on financial pressures exerted by some self-interested party."

Abbott contends that it has simply adjusted the price of Norvir to better reflect its value in the marketplace, and to ensure that the drugmaker has enough revenue for its continuing research and development of future AIDS drugs.